

Food and Drug Administration, HHS

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(NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[59 FR 63895, Dec. 12, 1994]

§ 184.1034 Catalase (bovine liver).

(a) Catalase (bovine liver) (CAS Reg. No. 81457-95-6) is an enzyme preparation obtained from extracts of bovine liver. It is a partially purified liquid or powder. Its characterizing enzyme activity is catalase (EC 1.11.1.6).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or may be examined at the Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200, and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in §170.3(o)(9) of this chapter to decompose hydrogen peroxide.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

[60 FR 32910, June 26, 1995, as amended at 69 FR 24512, May 4, 2004; 78 FR 14666, Mar. 7, 2013]

§ 184.1061 Lactic acid.

(a) Lactic acid ($C_3H_6O_3$, CAS Reg. Nos.: DL mixture, 598-82-3; L-isomer, 79-33-4; D-isomer, 10326-41-7), the chemical 2-hydroxypropanoic acid, occurs naturally in several foods. It is produced commercially either by fermentation of carbohydrates such as glucose, sucrose, or lactose, or by a procedure involving formation of lactonitrile from acetaldehyde and hydrogen cyanide and subsequent hydrolysis to lactic acid.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 159, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Avenue, NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an antimicrobial agent as defined in §170.3(o)(2) of this chapter; a curing and pickling agent as defined in §170.3(o)(5) of this chapter; a flavor enhancer as defined in §170.3(o)(11) of this chapter; a flavoring agent and adjuvant as defined in §170.3(o)(12) of this chapter; a pH control agent as defined in §170.3(o)(23) of this chapter; and a solvent and vehicle as defined in §170.3(o)(27) of this chapter.

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(2) The ingredient is used in food, except in infant foods and infant formulas, at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[49 FR 35367, Sept. 7, 1984]

§ 184.1063 Enzyme-modified lecithin.

(a) Enzyme-modified lecithin is prepared by treating lecithin with either phospholipase A₂ (EC 3.1.1.4) or pancreatin.

(b) The ingredient meets the specifications in paragraphs (b)(1) through (b)(8) of this section. Unless otherwise noted, compliance with the specifications listed below is determined according to the methods set forth for lecithin in the Food Chemicals Codex, 4th ed. (1996), pp. 220–221, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington DC 20418, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(1) Acetone-insoluble matter (phosphatides), not less than 50.0 percent.

(2) Acid value, not more than 40.

(3) Lead, not more than 1.0 part per million, as determined by atomic absorption spectroscopy.

(4) Heavy metals (as Pb), not more than 20 parts per million.

(5) Hexane-insoluble matter, not more than 0.3 percent.

(6) Peroxide value, not more than 20.

(7) Water, not more than 4.0 percent.

(8) Lysolecithin, 50 to 80 mole percent of total phosphatides as determined by "Determination of Lysolecithin Content of Enzyme-Modified Lecithin: Method I," dated 1985, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

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(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an emulsifier as defined in §170.3(o)(8) of this chapter.

(2) The ingredient is used at levels not to exceed current good manufacturing practice.

[61 FR 45889, Aug. 30, 1996, as amended at 78 FR 14666, Mar. 7, 2013]

§ 184.1065 Linoleic acid.

(a) Linoleic acid ((Z, Z)–9, 12-octadecadienoic acid (C₁₇H₃₁COOH) (CAS Reg. No. 60–33–3)), a straight chain unsaturated fatty acid with a molecular weight of 280.5, is a colorless oil at room temperature. Linoleic acid may be prepared from edible fats and oils by various methods including hydrolysis and saponification, the Twitchell method, low pressure splitting with catalyst, continuous high pressure counter current splitting, and medium pressure autoclave splitting with catalyst.

(b) The ingredient must be of a purity suitable for its intended use. The ingredient must also meet the specifications in §172.860(b) of this chapter.

(c) In accordance with §184.1(b)(1), the ingredient is used in food with no limitation other than current good